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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,783	11/14/2001	Yuch Ping Hsieh	90024	3137
9355	7590	10/04/2005	EXAMINER	
JACQUELINE E. HARTT, PH.D ALLEN, DYER, DOPPELT, MILBRATH & GILCHRIST, P.A. P.O. BOX 3791 ORLANDO, FL 32802-3791			GAKH, YELENA G	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/990,783

Applicant(s)

HSIEH ET AL.

Examiner

Yelena G. Gakh, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 14-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Amendment filed on 08/08/05 is acknowledged. Claims 1-25 are pending in the application. Claims 14-25 are withdrawn from consideration as directed to the non-elected invention.

#### ***Response to Amendment***

2. Objection of the specification is slightly modified and rejection of the pending claims under first paragraph of 35 U.S.C. 112 is withdrawn in light of the Applicants' arguments. Rejection of claim 13 under second paragraph of 35 U.S.C. 112 is withdrawn and rejection of the pending claims over the prior art is modified in view of the amendment.

#### ***Specification***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The specification is objected to as not containing "a written description of the invention, ... in such full, clear, concise, and exact terms as to enable any person skilled in the art" to practice the invention in its best mode. In particular, it is not clear, if the experiments for optimizing operating conditions (pages 6-7) are performed using samples with bacteria, or only with "a glove box having a known CO<sub>2</sub> concentration". It is not clear, if Figure 6 represents experiments conducted with real samples disclosed on pages 11 and 12. Since a series of preliminary experiments for optimizing conditions is presumably performed with simulated samples, this difference in the experiment set-up should be clearly indicated in the specification. Experiment #4 is not clear. It just demonstrates increasing the rate of absorption with increasing

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CO<sub>2</sub> concentration, which is an obvious fact. It is not clear, what this experiment has to demonstrate, and how it can be used for the “real” case.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. **Claims 1-13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stotzky (Method Soil Anal., 1965).

Stotzky teaches “microbial respiration”, including a method for measuring an evolution rate of CO<sub>2</sub> from a sample by a steady-state technique (page 1553) comprising colorimetric analysis, i.e. absorbing CO<sub>2</sub> by alkaline solution comprising pH indicator (pp. 1556-1557). Steady-state technique inherently comprises pre-incubation of the sample to reach the steady state of the system. Stotzky provides the following manual for performing measurements: “after flashing the residual air from the incubation vessel, attach the outlet tube of each vessel to a CO<sub>2</sub> collector containing a known volume of KOH or NaOH solution of a concentration such that not more than two-thirds of the alkali will be neutralized by the CO<sub>2</sub> to be collected. Attach CO<sub>2</sub> collectors to empty incubation vessels to serve as controls for CO<sub>2</sub> absorbed from atmosphere during the procedure. Replace the CO<sub>2</sub> collectors with fresh collectors periodically during the

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incubation period. After CO<sub>2</sub> absorption, rinse each bubble tower into the corresponding alkali container with CO<sub>2</sub>-free water, add an excess of **BaCl<sub>2</sub>** to precipitate the carbonate as BaCO<sub>3</sub>, add a few drops of **phenolphthalein indicator**, and titrate the unneutralized alkali with standard HCl directly in the container. Alternatively, make the titration in the absence of phenolphthalein using an automatic titrator. Titrate the CO<sub>2</sub> collectors from the control vessels concomitantly with those from the treatment vessels, thereby necessitating standardization of only the HCl” (page 1564).

Although Stotzky did not recommend shaking a vessel during experiments, following research demonstrated benefits of shaking the vessel, as demonstrated by the Applicants by the prior art and arguments provided in the response from 08/08/05.

Although Stotzky discloses a method of a “back titration” comprising titrating remaining NaOH, the method of direct titration is notoriously well known in the art, and would have been an obvious modification of Stotzky’s method. Stotzky discloses both open and closed systems. Stotzky indicates that for closed systems there should be a constant source of oxygen for bacteria digestion. Without the constant flow of oxygen the sample CO<sub>2</sub> evolution will be exhausted. For closed systems Stotzky specifically indicates performing experiments under steady-state conditions. It would have been obvious to apply direct titration in small aliquots and work with smaller samples to get more precise results.

Although Stotzky does not specifically teach repeating the same procedure several times and averaging the time increments, it would have been obvious for any routineer in the art to do so, because it is a conventional practice in any analysis to obtain data for the same process in order to use average for improving the results output.

### *Response to Arguments*

8. Applicant's arguments filed 08/08/05 have been fully considered but they are not fully persuasive.

The Applicants’ arguments regarding the prior art are not quite clear to the examiner. Stotzky teaches several variations of the method of measuring natural CO<sub>2</sub> evolution rate from samples containing microorganisms, including closed steady-state systems, and airflow open

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systems. He indicates specifically steady-state conditions for measuring evolution rate. To the examiner's understanding, the present invention discloses a slight modification of the method developed over 40 years ago, which comprises pre-incubation of the sample with the head-space environment (which is well known as steady state method), shaking the vessel (which was found to be beneficial in later research, as indicated by the Applicants), and titrating evolved CO<sub>2</sub> with NaOH containing phenolphthalein, the most common color indicator for acid-base titration, with precipitating BaCO<sub>3</sub> to eliminate more soluble sodium carbonate from the solution. The examiner would very much appreciate if the Applicants clearly explain the inventiveness of their acid-base titration method for measuring evolution rate of CO<sub>2</sub>. While the method can be found useful in the field, acceptance of the material of the disclosure by a peer-reviewed scientific journal cannot support non-obviousness of the method disclosed in the application.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

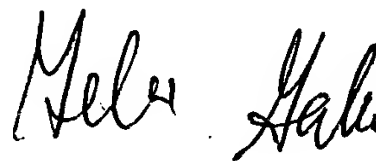
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

9/30/05

  
**YELENA GAKH  
PRIMARY EXAMINER**